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QUALITY OF ORAL DRUG FORMULATIONS OF ARTEMISININ-BASED COMBINATION THERAPY SOLD IN KATSINA STATE, NIGERIA

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ABSTRACT

There are increasing reports of substandard antimalarial drugs, and these have been a severe under-recognised public health problem especially in developing countries. For this reason, 21 samples of different brands of artemisinin-based combination therapies (ACTs) comprising of artemether/lumefantrine and artesunate/amodiaquine oral drug formulations that are available on sale in different hospital pharmacies and patent medicine stores in Katsina State, Nigeria were evaluated for microbial and chemical qualities. Microbial limit test (MLT) and assay for the content of the active pharmaceutical ingredients (APIs) using standard high performance liquid chromatography (HPLC) procedures were carried out as described in the official monograph of the United States Pharmacopoeia (USP) and the International Pharmacopoeia (IP). The results obtained had indicated that all the ACTs oral drug preparations were free from microbial contamination except one sample of artesunate-amodiaquine showing viable total combined yeasts/moulds count (TYMC) of 1.0 x 10^1 colony forming units (CFU)/g. All the samples complied with the USP and IP criteria for the microbiological quality of non-sterile oral dosage forms. On the other hand, 10 (47.6%) out of the 21 samples met the specific chemical quality standards. Moreover, 8 (57.1%) and 3 (42.9%) of the artemether/lumefantrine and artesunate/amodiaquine had active ingredient outside the set pharmacopoeial limit and, therefore, were none compliant to the IP specifications for percentage content. The presence of substandard ACTs may lead to possible therapeutic failure from the use of such kind of formulations, facilitate the development and spread of drug-resistance. There is the need for effective government regulation and adequate enforcement on the production, distribution and sales of good quality medicines.

Keywords: Artemisinin-based combination therapy, Microbial contamination, Active pharmaceutical ingredients, United States Pharmacopoeia, International Pharmacopoeia

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